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AGRICULTURAL BIOTECHNOLOGY ANNUAL

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Report Highlights:
Despite the ending of an 18-month de facto moratorium on biotechnology approval and evaluation in July 2008, there have been no approvals of new Living Modified Organisms (LMO) events in the country. A new regulatory system for LMOs has been developed. There are three events approved for commercialization in Uruguay: one soybean variety (MON 40-3-2) and two corn varieties (MON 810 and Bt 11).

Section I. Executive Summary:

According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), Uruguay now ranks 9th among countries in the number of acres planted with biotech varieties, as production of crops has increased in recent years. In 2008, 620,000 hectares were sown with biotech varieties.

In January 2007, the President of Uruguay signed a decree imposing a de facto moratorium for 18 months on the review and approval for new events. The moratorium was lifted in July 2008, with the derogation of Decree 249/00 and the creation of a new regulatory framework by Decree 353/008. No new approvals have been granted since then.

The new regulatory framework requires consultations with a broad range of specialists and stakeholders (including civil society), and it involves participation of several ministries as well as various commissions.

Another addition to the new regulatory framework is a fee, which will be paid by the applicant seed company. The cost varies according to the level of evaluation requested.

Section II. Biotechnology Trade and Production:

In recent years Uruguay has experienced an agricultural revolution, with crop area estimated at several times the harvested area of 2000/2001. Sustained world-wide demand and favorable local conditions for the expansion of crops (available land, efficient technicians and companies, and stability of the business framework) are key factors behind the phenomenon.

The suspension of new biotech event approvals has had its largest impact on corn production since new varieties suitable for conditions in Uruguay are not yet being approved. Also, climate change experts predict that weather conditions in Uruguay might become more severe – particularly drought. Those potential conditions and changes in weather patterns would make it even more critical for farmers to have access to seeds better adapted to more difficult conditions.

There are currently three authorized biotech events for production and commercialization in Uruguay. They include:

Soybeans, event 40-3-2 (approved in 1996)
Corn, event MON 810 (approved in 2003)
Corn, event Bt 11 (approved in 2004)

Uruguay allows field testing of biotech crops.

Soybeans

Soybean harvested area increased from 77,000 hectares in MY2002/03 to over 650,000 hectares estimated for 2009/10. Approximately 99 percent of total soybean area is planted with Round-up Ready soybeans. Potential area for increased soybean production is fairly limited compared to neighboring countries.

Corn

The authorization for imports and commercialization of Monsanto's insect-resistant corn (variety MON 810) was approved by the Government of Uruguay (GOU) in 2003. Bt 11 corn was approved in 2004. The approval of both varieties aroused opposition among environmentalists and other groups.

Evolution of area planted (conventional corn and Bt)

Year	Total Area (has)	Bt Area (has)
2003	44,923	1,150
2004	60,601	23,300
2005	53,400	30,000
2006	85,000	46,000
2007	140,000	95,000
2008/2009	135,000	110,000

Rice

No biotech rice varieties have been approved. Adoption in Uruguay of rice varieties containing biotech events will depend, almost exclusively, on the acceptance of these events in Uruguay's export markets. Rice producers are very open to the idea of biotechnology, but they are unlikely to adopt new technologies that may jeopardize their export markets.

Section III. New Technologies:

Currently, Uruguay has no genetically engineered animals, and they are not yet in the process of developing regulation.

Section IV. Biotechnology Policy:
Uruguay's Historical Evolution of the Biosafety Regulatory System for LMOs

International Framework

1993	Signed the Convention on Biological Diversity
1994	Adopted UPOV-78
1995	Became member of the World Trade Organization, WTO
2001	Adhered to Cartagena Biosafety Protocol
2008 -2009	Is in the process of Parliamentary ratification

National Framework

1996	Approved Soybean 40-3-2

2000	Signed Decree 249/2000 - The Committee for the Risk Assessment of Genetically Modified Plants (CERV) is created establishing the procedures for the request of authorization to use LM plants in different fields.
2003	Granted authorization for production and import destined to direct consumption or transformation of MON 810.
2004	Granted authorization for production and import destined to direct consumption or transformation of Bt 11.
2006	Suspended use, production and commercialization of genetically modified sweet corn seeds.
2007	Signed Decree 037/007 - The moratorium imposed the suspension of new requests for LMOs for 18 months, and created an inter-ministerial working group whose goal was to define the national biotechnology policy.
2008	Signed Decree 353/008 – Suspension of moratorium, creation of new regulatory framework through an inter-ministerial network.
2009	National Seed Institute issued new forms to be completed by requesting companies.
2009	Biosafety Law still pending.

The GOU first formally endorsed the use of biotechnology and took concrete steps the oversight and regulation of biotechnology products by creating a risk assessment commission for living modified organisms (LMOs) in 1995. The first biotech authorization occurred in 1996 when the use of biotech soybeans was authorized. In 2000, Decree 249/00 created the Risk Assessment Commission of Genetically Modified Plants (CERV in Spanish) and established a regulatory framework to authorize the introduction, use, and manipulation of LMOs.

On January 29, 2007, the GOU decreed "the suspension of evaluation of new requests for authorization to introduce events of living organisms of vegetable origin and their genetically modified parts for any of the purposes defined in decree 249/2000, by the Commission of Risk Assessment of Genetically Modified Vegetables". This moratorium applied to the introduction of new biotech events for both production and field testing.

During that period, a group composed of representatives of different Ministries (Agriculture, Health, Economy and Environment) re-evaluated and strengthened the current policy. Their work focused on social issues, scientific research, and agricultural production. The timeframe for the re-evaluation process was set for 18 months.

End of the Moratorium for New Biotech Events

The moratorium was lifted in July 2008, with the derogation of Decree 249/00 and the creation of a new regulatory framework by Decree 353/008. No new approvals have been granted since

then. (See following sections for details about current regulatory procedures).

Between the prior suspension of approvals in 2006 and until the National Coordination Committee (CNC in Spanish) developed a proposal for a biosafety framework, there were at least 3 years during which Uruguay did not approve or conduct field tests on new events.

Current Regulatory Procedure

Through Decree 353/008, Uruguay developed a new regulatory scheme for evaluation of new LMOs, which requires participation of several Ministries as well as a complicated interaction of various groups.

The regulatory procedure includes risk assessment, risk management and risk communication. It requires consultation with a broad range of specialists and stakeholders (including scientists and representatives of civil society) apart from those usually included (toxicologists, nutritionists, molecular biologists, and plant breeders). The final decision on the release of biotech seeds, however, falls within the scope of an inter-ministerial National Biosafety Commission (called GNBio), which is chaired by the Minister of Agriculture.

Approvals from Argentina, the United States, and Canada are taken into account as a precedent in the approval evaluation process.

A description of the approval process and of all intervening groups follows:

National Biosafety Commission (GNBio)

Members: The Minister of Agriculture, MAG, (chair); Minister of Health, MSP; Minister of Economy and Finance, MEF; Minister of Housing, Territorial Ordering and the Environment , MVOTMA; Minister of Foreign Affairs, MRREE; and Minister of Industry, Energy and Mining, MIEM.

Functions: It is the last responsible entity to make decisions over the submitted request. The cabinet takes into account, among others, all macro political aspects. It has the authority to define policies to be followed with respect to biosafety in all scopes of LMO application.

Commission for the Risk Management (CGR)

Composed by one delegate of each of the ministries represented within GNBio. This commission is also chaired by the representative of the Ministry of Agriculture.

Functions: It advises GNBio on LMO~~s~~ biosecurity issues; elaborates reference terms for risk assessments; participation process; is responsible for follow-up and monitoring of authorized events and is tasked with preparing a bill for a

National Biosafety Law for LMOs within the timeframe of one year.

Evaluation of Risk in Biosecurity (ERB)

Members: Composed of experts proposed by the CGR and by designated GNBio among specialists in the different areas of risk assessment.

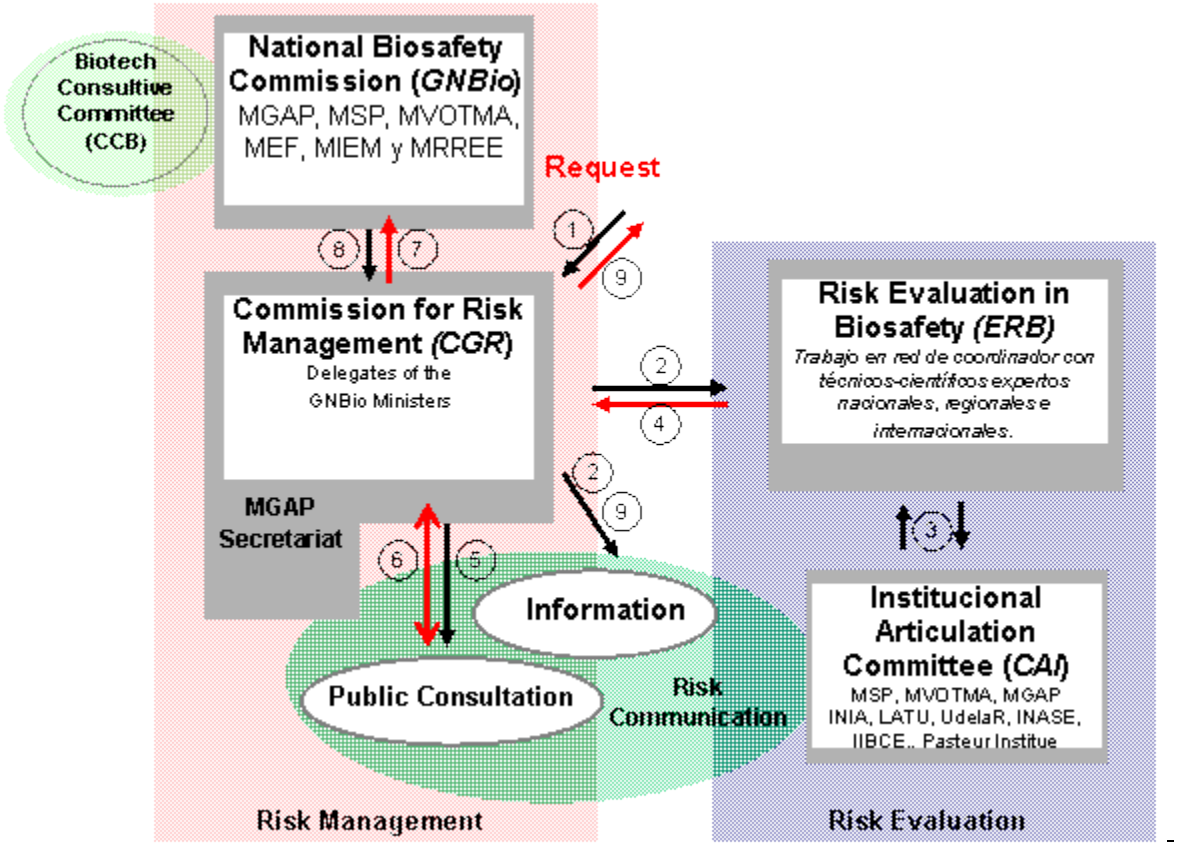
Functions: Identifies national and/or regional capacity for network collaboration.
The Commission is responsible for considering, on a case-by-case basis, the potential risks and benefits of each new biotech product; assure case-by-case risk assessment evaluation based on sound scientific methods; writes an operational plan (pre-report) of risk assessment according to CGR directives; advises CGR based on the results of the analysis of risk assessment, and provides information during the consultation process.

Institutional Articulation Committee (CAI)

Members: Technical experts from different institutions such as the MAG; MSP; MGAP; MVOTMA; Ministry of Education; Technological Laboratory of Uruguay, LATU; National Institute of Agricultural and Livestock Research, INIA; National Seed Institute, INASE; Pasteur Institute; and University of the Republic, UDELAR.

Functions: Performs technical risk assessment of new events; prepares a technical report. The group will be selected and coordinated by the ERB coordinator.

Summary of the Authorization Process



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- CGR receives a new request.
- CGR elaborates reference terms case by case and
    - Delivers to ERB for risk assessment.
    - Informs the civil society (through public channels).
- ERB elaborates proposal for risk assessment, calls CAI, adjusts (or not) the proposal, initiates the evaluation and/or analyzes results of the evaluation.
- ERB prepares report for CGR.
- CGR elaborates recommendation for GNBio considering report from ERB and other factors. Begins open consultation with civil society.
- CGR receives and replies comments of civil society.
- CGR elaborates final report with recommendation to GNBio.
- GNBio makes the final decision.
- CGR informs final decision to requestor and to civil society thru public consultation.

Public consultation

Public consultations are planned to evaluate the impact of the LMO authorization, and they occur at three different levels:

- *Definition of policies*:

Provide collaboration to GNBio on the design and follow up of biosafety policy for LMOs. The institutions, private sector and civil society will be invited to designate a representative.

- *Authorization process for requests of new events*:

Information stage: Once the request is received, it will be announced to the society through channels of public information.
Consultation Stage: Prior to the recommendation to GNBio, results are informed through public hearing and there is a period open for suggestions.

- *Control and claims of new authorized events*:

Reception of claims through a technical secretariat that will channel the requests to the institutions in charge of monitoring and control.

Applications

- Contained use (laboratory scale)
- Field trials
- Production and commercial use for direct consumption or transformation
- Importation or exportation with specific destination for direct consumption or transformation.

Distribution of responsibilities

The applicant pays: Every request entails an expense, which has to be assumed by the applicant. Among other things, this expense would be used in the event there is a need to hire specialized technical staff for specific studies. The financing of the performance evaluations of an event in consideration (evaluations at the level of experimental fields) could be assumed in its entirety or partially by the seed companies requesting the authorization of the event under consideration.

Cost ranges: UY$ 11,650 (approx. US$ 492) for laboratory scale evaluation, to UY$ 163,100 (approx. US$ 6,880) for evaluation for commercial use, importation or exportation.

The applicant delivers basic information: Two copies in Spanish language must be submitted, one hard copy and the other one in digital format.
The form may be found at: **http://www.inase.org.uy/**

Cartagena Biosafety Protocol

Uruguay has yet to ratify the Cartagena Biosafety Protocol to the 1992 Convention on Biological Diversity (CBD). Until the Protocol's entry into force (September 2003) Uruguay operated within the framework of the GRULAC Group (Group of Latin American and Caribbean Countries) for pursuing the implementation of the biosafety principles outlined in the Cartagena Protocol.

Uruguay, a member of the former Miami Group, has strongly concurred with USG positions on biotechnology at international fora in the past, and is highly likely to continue to do so.

Traceability

Issues related to biotechnology such as traceability and labeling (T&L) of biotech seeds are currently the focus of an internal debate that is being carried out at the governmental level.

With respect to the European Union's T&L regulations, contacts at the Ministry of Livestock, Agriculture and Fisheries, (MGAP) report that traceability is a difficult issue since it is more a commercial concern, rather than a scientific one. These contacts report that since Uruguay is very dependent on the European market as an outlet for its agricultural products, some kind of traceability system will probably be necessary. However, they have repeatedly made it very clear that the GOU would not support mandatory requirements in international fora.

Labeling

Uruguay has adopted voluntary labeling of **"GM"** or **"non GM"** products, as applicable to those food products for which an analysis of the final product can determine the presence of genetic modification.

Stacked genes

Policy is similar to the US.

Coexistence

No policy. The European Union's regulations are currently being used on an informal basis, but adapted to Uruguay's framework.

Refuges

It is mandatory that 10% of the planted area be kept as a refuge. Uruguay is a small country and the National Seed Institute (INASE) visits the producers in person, thus maintaining a strict control.

Royalties

Farmers are required to pay extended royalties on all biotech seeds.
Uruguay's seed law makes a provision for the use of seeds in subsequent years. Seed companies require producers to sign a contract promising to pay royalties the next year.

Trade Barriers / Pending legislation

On several occasions during the past administration, the opposition publicly urged the former president to halt the liberalization of LMO crops based on the country's goal of becoming a "natural country," and on the application of the precautionary principle.
A Biosafety Law is still pending, and it is estimated that after the upcoming presidential elections this year, a bill will be presented to Congress.

Section V. Marketing:
There is still misunderstanding and misperception about the safety of biotech plants and foods on human health and the environment. NGOs have opposed the introduction of biotech crop planting and strongly request labeling on biotech products. There is a scattered and unorganized, movement against biotechnology led by NGOs. A major issue is the potential conflict between production of biotech crops and the "Uruguay Natural" marketing campaign for products from Uruguay.

Consumer associations have raised concerns about possible negative impacts on human health and the environment. They mainly advocate labeling and traceability and local field trials of biotech seeds prior to approval. They also question the potential for toxicity and allergenicity of biotech products.

There is some resistance in the meat industry to the approval of White Clover, one of the events that was under research before the moratorium. Clover is used in pastures, and for this reason "natural meats" will cease to be reliably "natural" according to their arguments. The largest potential issue in this area is for the sheep industry. Clover is used to feed sheep exported to Middle Eastern countries, where biotechnology is highly controversial.

According to private sources, it is very likely that the first events that would be submitted for evaluation are: GA21 x Bt 11; NK603 x MON 810; Hercullex and Hercullex x NK603.

Post is unaware of any relevant, specific studies on the marketing of biotechnology products in the country.

The Uruguayan Seed Chamber has conducted a survey among farmers
on the use of Bt corn seed that provided the following conclusions:
- Bt corn has a high penetration level (67% of total area planted).
- Bt seed provides good performance compared to conventional seed.
- Total cost of pest control is lower with the utilization of Bt corn.
- 86% of consulted farmers are more satisfied with the pest control with
Bt seed that conventional seed.
- 9 out of 10 farmers do not report any damage related to the use of Bt corn,
- 100% of consulted farmers use refuges.

- 30% of consulted farmers plans to increase the area dedicated to Bt corn,
50% reported they will maintain the same area, and 18% reported will diminish the area (the reasons voiced are not related to Bt seed).
- Farmers are even more optimistic when talking about the future of Bt seeds. 86% believe that global area planted will increase in the next 5 years, and 66% of them reported that they will personally increase the use of Bt seed in that timeframe.

Section VI. Capacity Building and Outreach:
Proposed Activities

FAS Buenos Aires proposes a continuation of education and outreach as well as a more targeted information campaign. Specific activities may include:

- Workshops in different cities to target audiences around the country.

- Coordination with local universities to demonstrate the benefits of biotechnology in Uruguay.

- Continue Cooperator, Cochran and International Visitor program activities.

- Special activities designed for consumer association leaders and consumers in general.

- Workshop especially directed to medical doctors and nutritionists, explaining biotech products.

-Workshop on risk assessment that will be directed to Argentine, Paraguayan and Uruguayan experts.